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COMMITTEES:

JUDICIARY

ARMED SERVICES

Congress of the United States

House of Representatives Washington, DC 20515—1004

May 11, 2011

Dr. Donald Berwick Administrator Centers for Medicare and Medicaid Services 7500 Security Blvd. Baltimore, MD 21244

Dear Dr. Berwick:

We are writing to you today to express our deep concern over onerous cost-sharing requirements that Medicare Part D prescription drug plans are increasingly imposing on beneficiaries. This matter is particularly relevant in light of the ongoing period of economic difficulty and the recent release of the CMS Plan Year 2012 Draft Call Letter for Medicare Part D.

Specifically, we are troubled by the proliferation of "specialty tiers" for high-cost drugs that treat conditions such as rheumatoid arthritis, multiple sclerosis, and hemophilia. Unlike generic and preferred brand drugs that generally require co-pays, therapies placed on a specialty tier are subject to coinsurance, requiring the beneficiary to pay a percentage of the drug's cost. This can amount to patients having to spend thousands of dollars to obtain needed medication, leading many to forego or alter treatment and suffer worse health outcomes that ultimately increase costs for Medicare and the health care system overall.

For 2011, CMS retained a "specialty tier" threshold of \$600 for the fourth year in a row in spite of rising drug prices and the January 2010 GAO report "Medicare Part D: Spending, Beneficiary Cost-sharing and Cost-Containment Efforts for High Cost Drugs Eligible for a Specialty Tier" (GAO-10-242) that found the median price of drugs on the specialty tier, using 2007 data, was \$1100. Therefore, we were particularly alarmed when the 2012 Draft Call Letter noted that the threshold would remain at \$600 for a FIFTH year. Because of the rising costs of all drugs, maintaining this low threshold will place more drugs on the specialty tier and subject vulnerable beneficiaries to higher out-of-pocket costs. The rationale for this decision was not included – or even implied – in the call letter. This decision was especially puzzling in light of concerns about the threshold expressed to CMS by Members of Congress and various consumer and patient groups representing Medicare beneficiaries.

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Furthermore, CMS has never publicly explained the methodology for setting the limit for inclusion on the specialty tier. Again, CMS has been asked to clarify this process but to date has not responded. Therefore, we strongly urge you to provide a clear, easily understood explanation for CMS' process to arrive at this decision. We ask that you explain what criteria are involved, what data is analyzed and what role the effect on beneficiaries plays in the decision-making process. The last item is of particular importance because it currently appears that beneficiaries are not considered at all.

A clear, concise explanation of the methodology for determining the threshold is also of utmost importance in the interest of transparency, particularly at a time when many citizens feel the government is not working for or listening to them and Members of Congress often feel they have little insight into agency workings. With a program like Medicare, which affects enrollees in terms of health outcomes, finances and quality of life, it is particularly critical that people understand the rationale for decisions and feel that government oversight is being conducted in their best interest. Similarly, Members of Congress must be kept fully informed about policies that have such a significant, direct impact on their constituents.

Thank you for looking into this matter, which is only going to become more important as biologics and other high-cost drugs that offer hope to the millions suffering with chronic conditions become an increasingly large share of the market. As that happens, more and more drugs will be subject to these burdensome cost-sharing requirements, often denying patients access to the very treatments they desperately need. We are certain you share our concern about this as well as our desire to ensure such drugs' availability to those who need them.

We look forward to receiving your response.

Sincerely,

Hank Johnson

Member of Congress

Eddie Bernice Johnson Member of Congress Sam Farr

Member of Congress

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